510(k) Summary

JUL 11 2006

Applicant Information

Submitter

Steven H. Warnock, M.D., P.C.
9829 S. 1300 E.
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Contact information

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Submitter Registration Number: K060986

Device Name and Classification:

Common Name:	Infant Sleep Positioner
Classification Name	Holder, Infant Position, Code FRP, CFR 880.5680
Trade Name:	Head Bed™
Class:	Class 1

Device Description:

The Head Bed device is a U-shaped soft polyurethane foam cushion covered in flame retardant cloth material. Outside dimensions are 17.5cm (w) x 18.5cm (l) x 4cm (h). Inside dimensions are 13.5cm (h) x 6.5cm (w). The device is adequately soft so as to provide support for the infants head without being abrasive. The removable cloth cover is flame retardant and machine washable.

Intended Use:

Deformational plagiocephaly is an abnormal flattening of the back of the infant's head resulting from lying in one position. Some medical conditions predispose infants to this condition. Frequent changes in head position can help prevent or correct deformational plagiocephly. The Head Bed device is intended for use as an infant sleep positioner. The Head Bed device is used to position the head so as to aid in the prevention of deformational plagiocephaly. It is intended for use in infants less than 6 months of age or in those infants who cannot roll from back to front. The device is placed on the mattress, around the head to control head position. This selective positioning of the head allows some control over the forces that create flattening of the head.

Predicate Device:

The subject device is substantially equivalent to a predicate device NightForm Infant Sleep Positioner.

Predicate Comparison:

Comparison	Head Bed™ Positioner	NightForm™ Infant Sleep Positioner
Application	Sleep positioning	Sleep positioning
Target population	Infants 0-6 months	Infants 0-9 months
Purpose	To maintain infant sleep position for prevention of deformational plagiocephaly.	To maintain infant sleep position for prevention of deformational plagiocephaly.
Materials	Fire-resistant foam and a fire retardant fabric cover with Velcro closure.	Fire-retardant foam and fabric (cotton or poly/cotton blend), mechanical hook & loop fasteners, nylon zipper.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2006

Dr. Steven H. Warnock
President
Steven H. Warnock, M.D.
9829 South 1300 East, Suite 200
Sandy, Utah 84094

Re: K060986
Trade/Device Name: Head Bed™ Infant Positioner
Regulation Number: 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: March 6, 2006
Received: March 18, 2006

Dear Dr. Warnock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, PhD.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060986

Indications For Use

510(k) Number (if known): K060986

Device Name: Head Bed™ infant positioner

Indications For Use:

The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AWJ

...on Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number: K060986